Declaration under 37CFR 1.132

USA Patent Application 09/857,611

I Gregor Bruce Yeo Christie, a co-inventor of the invention defined in USA patent application 09/857611 hereby declare that:

1. I have reviewed and understand the contents of the examiners report mailed 2nd April 2002.

2. I have read and understood patent specifications JP-8-325447['447], JP-8-245836 ['836], USA 5322866 [Mayer] and USA 5363777 [Tomka]

3. I hold a Bachelor of Engineering degree(chemical) from the University of Queensland and a Doctor of Philosopy (Chemical Engineering) from the University of Melbourne. I am a member of the Institute of Engineers Australia, The Royal Australian Chemical Institute and Australian Institute of Packaging. I have worked for one year as a graduate engineer for BP(British Petroleum). I worked for four years in The Surface Science and Colloid Centre at Swinburne University where the work involved diffusion, gas adsorption and energetic site mapping in porous materials. The work involved consultancies for Mobil Oil, a UK Carbon Company and BP. I spent three years conducting the experimental work for my PhD thesis at the University of Melbourne Chemical Engineering Department which involved the measurement of the flow properties of heterogenous systems containing porous particles. I was employed by the Commonwealth Scientific & Industrial Research Organisation (CSIRO) to lead a polymer packaging group to develop polymer processing technologies and active packaging and provide packaging expertise to the Australian Horticultural Industry. I have acted as a consultant in testing and developing polymer packaging films for a large number of Companies including Dow Chemical, Pacific Dunlop, Amcor, Pratt Industries, ICI, Exxon, Mobil and many other small companies. I am presently employed by Swinburne University as a lecturer in Chemical Engineering. I am the inventor of the USA patents 5,807,630 and 5891376.

4. There have been many attempts to formulate useful starch based biodegradable polymers. Degradation of polymers occurs by way of a number of processes which are always active in the environment, including exposure to ultraviolet radiation, mechanical forces, water solubility and biological attack by enzymes. Most biodegradable polymers and particularly those disclosed in the cited patents, rely on enzymes released from micro-organisms present in the environment to effect degradation of the polymer. Water solubility accelerates degradation of the polymer because it softens and separates the polymer to allow a more rapid enzyme attack on the polymer. Starch with added water, extruded under the right conditions is water soluble and this can be disadvantageous in some applications where biodegradability is important but resistance to water damage is also desirable. In order to be acceptable as viable alternatives to existing non biodegradable plastics the strength characteristics toughness and flexibility properties of biodegradable polymers must be equivalent to the properties of the non biodegradable polymers currently in use.

5. Polymers having these characteristics have been developed by blending starch with water soluble and water insoluble polymers other than starch, but the acceptance has been limited because the cost of the biodegradable polymers has not been comparable to the costs of the non biodegradable polymers.

6. Other difficulties encountered with starch polymers are processing difficulties caused by incompatibility between the starch components and the blended polymers. Because of water content in the starch, foaming of the mixture in the extruder can occur. Also the starch cakes on the inside of the extruder and creates a cleaning difficulty.

7. In formulating a polymer for a particular application not only must the desirable properties be produced but the processability of the formulation and the cost of the formulation must also be acceptable. It is often the case that in overcoming one problem such as processability that desirable properties in

the final polymer are compromised or if processability and properties are acceptable the costs are not price competitive with the non biodegradable polymer.

8. Thus to develop a suitable biodegradable formulation for a particular application a substitution of a component or a change in proportions of a component can make a significant difference in some or all of processability, functional performance or price in an unpredictable way. The usual practice when developing a starch/water/ synthetic polymer system is to produce a large number of a large number of samples varyingin concentration, ingredients, and processing conditions and then measure the mechanical properties of the samples. In my experience there is no predictable out come from changing polymer types particularly when changing from water insoluble to water soluble polymer components.

9. This invention provides two formulations for two different applications. The first application is packaging trays for products such as biscuits or chocolates. The formulation developed uses
   a) 8 to 80% of a starch modified to include an hydroxyalkyl C_{2-6} group or modified by reaction with an anhydride of a carboxylic acid
   b) 4 to 11 % of a water soluble polymer selected from polyvinylacetate and polyvinyl alcohol
   c) up to 12% added water
   d) 0 to 12% of a polyol plasticiser
   e) 0.1 to 1.5% of a C_{12-22} fatty acid or salt
   f) the balance being a natural starch

10. In the second application this invention provides a film formulation suitable for blowing into a film . the formulation developed uses
    a) 8 to 80% of a starch modified to include an hydroxyalkyl C_{2-6} group or modified by reaction with a an anhydride of a carboxylic acid
    b) 4 to 11 % of a water soluble polymer selected from polyvinylacetate, polyvinyl alcohol and copolymers of ethylene and vinyl alcohol

c) 10 to 16% of a poyol plasticizer

d) up to 12% added water

e) 0.1 to 1.5% of a C_{12-22} fatty acid or salt

f) the balance being a natural starch

11. Both formulations were developed from extensive research to find an optimum mix that gave satisfactory properties and processability at a cost that was comparable to that of currently used polymers. The fast biodegradability of the blends is dependent on both the starch and the other polymer component being water soluble. The major reduction in cost was achieved by reducing the amount of polymer in component b).

12. Both formulations allow the extrusion processing to operate without caking of the extruder and without the need to vent the die. The polymers are blended for processing to form a melt at relative low temperatures of 130 °C to 160 °C. The die temperatures for the process can.be maintained within the range of 85 °C to 105 °C which is much lower than was possible with prior art formulations. Operating at lower die temperatures reduces the need for venting and improves the performance characteristics of the polymer blend. These processing characteristics are derived from the combination of modified starch, natural starch and lower proportions of the water soluble non starch polymer as well as the inclusion of water as the essential plasticizer and a polyol as an optional additional plasticizer.

13. The JP '447 reference by Chisso discloses biodegradable polymers that must include a modified starch that could include the specific modified starch defined in this invention. In addition the composition must include two other polymers namely 10 to 30% by weight of an ethylenevinylalcohol polymer and 50 to 60 % of a polycaprolactone. It also requires the use of glycerol and a fatty acid amide. Polycaprolactone and ethylenevinyl alcohol are not water soluble polymers. The cost of the formulation is much greater than that of either of the formulations set out in paragraphs 9 and 10 because of the low content of starch and the high content of expensive polymers such as poly

caprolactone. There is no suggestion that acceptable biodegradable polymers could be obtained by substituting starch for the polycaprolactone.

14. The JP'836 reference also by Chisso discloses a film formulation which may contain 5 to 80 % of a raw or modified starch 0.5% to 30% water and 4.4 to 49 % of an ethylene vinyl acetate copolymer or a polycaprolactone. Again both these polymers are not water soluble. The content range of water is much wider than proposed in the formulations of my invention and I do not believe that all of them would produce acceptable films. There is no explanation of what proportion of chemically modified starch should be used. The polymers proposed are all different to those listed in component b) and there is no suggestion that they could be substituted by water soluble polymers. There are such a large number of possible compositions and no explanation of how the components affect the properties, that it is impossible to say that there is any suggestion of the formula of paragraph 10 in this disclosure.

15. Mayer discloses forming a blend of raw starch and 20 to 80% polyvinyl alcohol or ethylene vinyl alcohol and talc and combining that with a mixture of water and glycerol to produce blown films. The minimum quantity of polymer other than starch is greater than the maximum required in the formula given in paragraph 10 above. Although zinc and calcium stearates are used as nucleating agents they are disclosed as alternatives to talc. The processing requirements disclosed in Mayer use a minimum die temperature of 110 °C (see examples1 and 3) whereas the formulation of my invention allows processing at die temperatures below 105 °C.

16. Tomka discloses a high temperature process for processing starch. The starch material used may include chemically modified starch. An important requirement is that no water is added to the starch. Tomka processes the starch at temperatures from 150 °C to 300 °C under conditions that have no water. As pointed out in column 12 Tomka eliminates foaming in the extruder by controlling water content and avoiding added water. There is no discussion or suggestion in Tomka as to the possibility of using chemically modified

starches for processing at lower temperatures or in the presence of added water.

17. In paragraph 3 of the office action the examiner states that the Japanese references disclose compositions that fall within the ranges claimed for my invention. As pointed out in paragraph 13 above the JP '447 reference also requires the use of a large proportion of polycaprolactone which is not a component of the formulation of my invention. The JP'836 reference also uses different non starch polymers, which are not water soluble, for blending.

18. Formulating polymer blends is not a simple process and it is not a routine matter to vary components within a formulation because it is difficult to predict what effect the changes will have on the functional properties and processing requirements of the formulation. It is and was not possible to predict what the consequence would be of changing the non water soluble non starch polymers such as polycaprolactone in the formulations of the Japanese references to a water soluble polymer. It was also not possible to predict that smaller quantities of the non starch polymers would be viable.

19. In paragraph 4 of the office action the examiner asserts that it would be obvious to combine the disclosure of Tomka that chemically modified starches could be used with the disclosure of Mayer. However a skilled polymer chemist would not combine these two disclosures. Tomka clearly states that water is to be eliminated and not added whereas Mayer does allow for the addition of water. Neither reference teaches that the formulations could be processed at lower temperatures and be used in extruders with die temperatures in the range of 85 to 105 °C. Further neither references teach the use of a modified starch could allow the amount of non starch polymer to be reduced and thus reduce the cost of the formulations.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false

statements and the like so made are punishable by fine or imprisonment or both under 18 U. S. C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon

21 day of May 2002

Gregor Bruce Yeo Christie